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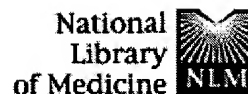
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## Advances in vinca-alkaloids: Navelbine.

**Marty M, Extra JM, Espie M, Leandri S, Besenval M, Krikorian A.**

Institut de Recherche sur les Leucemies et les Maladies du Sang, Service d'Oncologie Medicale, Hopital Saint-Louis, Paris, France.

Vinorelbine (Navelbine) is a new semisynthetic vinca alkaloid which chemically differs from vinblastine by substitutions on the catharantine moiety of the molecule. It has shown promising experimental antitumor activity against experimental murine tumors as well as continuous cell lines of human neoplastic origin and human tumor xenografts in nude mice. Acute subacute and chronic toxicity extensively studied in rodents, dogs and primate has shown that hematotoxicity was almost the sole side-effect; neurotoxicity appears very limited. Almost exclusive affinity of NVB for mitotic tubulin and tubulin associated protein accounts for this pattern of toxicity. Phase I and II studies have been conducted in humans. Dose limiting side-effect appears to be neutropenia: the drug is slightly emetogenic, induces little alopecia, almost no neurotoxicity, and no other toxicity. Although preliminary, results of phase II studies already suggest significant activity of NVB in non small lung cancer (33% response rate in 78 evaluable patients), advanced breast cancer (53% response rate in 33 pts without significant chemotherapy for the target progression) and Hodgkin's disease (90% response rate after 4 weekly courses in 31 pts). Thus extensive pharmacological studies and ongoing clinical studies confirm that chemical modifications of the catharantine moiety of vinca alkaloid can lead to active agents with broader spectrum of activity and easily manageable side effects.

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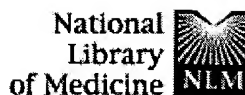
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## Pharmacokinetics of vinorelbine in patients with liver metastases.

Robieux I, Sorio R, Borsatti E, Cannizzaro R, Vitali V, Aita P, Freschi A, Galligioni E, Monfardini S.

Laboratory of Clinical Pharmacology, Istituto Tumori Centroeuropeo, Centro di Riferimento Oncologico, Aviano, Italy.

**BACKGROUND:** The main elimination pathway of vinorelbine is hepatic metabolism, and the clearance of vinorelbine could be reduced in patients with liver metastases. **OBJECTIVES:** To study the pharmacokinetics of vinorelbine in patients who have advanced breast cancer with or without liver metastases and to study the relationship between hepatic function and vinorelbine clearance. **PATIENTS AND METHODS:** We studied 29 patients with advanced breast cancer: 19 with liver metastases and 10 control patients with extrahepatic metastases (mean age, 61 years; age range, 38 to 81 years). The vinorelbine dose was 30 mg/m<sup>2</sup> as a short intravenous infusion; the dose was reduced by 50% in patients with bilirubin > 2 mg/dl. Patients were classified by ultrasonographic estimation of the liver volume replaced by tumor (%LVRT). Standard liver function tests and a monoethylglycinexylidide test (a quantitative liver function test based on lidocaine metabolite formation) were performed. Vinorelbine was assayed in plasma by HPLC with fluorescence detection. Vinorelbine determination was impossible in two patients with more than 75% LVRT because of interferences. Pharmacokinetic parameters were calculated with a noncompartmental method and compared by means of the Kruskal-Wallis test. **RESULTS:** A lower vinorelbine clearance rate was observed in the five patients with more than 75% LVRT (22.9 L/hr/m<sup>2</sup>) compared with the 10 patients with no liver metastases (48.0 L/hr/m<sup>2</sup>) and the 12 patients with 25% to 75% LVRT (45.3 L/hr/m<sup>2</sup>). Terminal elimination half-life and apparent volume of distribution were not significantly different among groups. The monoethylglycinexylidide test had a significant correlation with vinorelbine clearance. ( $r^2 = 0.70$ ;  $p = 10^{-4}$ ). **CONCLUSIONS:** These results support vinorelbine dose reduction in patients with severe liver failure but not in patients with moderate secondary liver involvement. The monoethylglycinexylidide test may prove to be useful for vinorelbine dose individualization.



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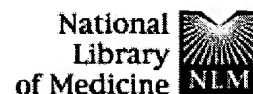
## Cytotoxicity, cell cycle kinetics and morphonuclear-induced effects of Vinca alkaloid anticancer agents.

Pauwels O, Kiss R, Pasteels JL, Atassi G.

Laboratoire de Pharmacologie Cellulaire, Institut de Pharmacie, Universite Libre de Bruxelles, Belgium.

The effects of four Vinca alkaloids (vinblastine, vincristine, vindesine and vinorelbine) on three neoplastic cell lines (the MXT mouse mammary cell line and the T24 and J82 bladder cell lines) were studied at three biological levels, i.e. cell proliferation, cell cycle kinetics and morphonuclear characteristics. These effects were studied by means of digital cell image analysis on Feulgen-stained nuclei. The aim of the present work was to characterize the effects specifically induced by Vinca alkaloids as compared with those obtained previously with other pharmacological classes of anticancer drugs. The results show that Vinca alkaloids inhibit the cell proliferation of neoplastic cell lines at a concentration of  $10^{-8}$  M except in the case of the J82 cell line, for which only a slowing down of cell proliferation was observed. Concerning the cell cycle kinetics, the results show that the Vinca alkaloids induce an accumulation of cells in the mitosis phase. This accumulation of mitotic cells was maximal after 15 h incubation in the presence of the drugs. A study of the morphonuclear-induced effects of Vinca alkaloids showed that the variance of the optical density (VOD) is strongly influenced by these Vinca alkaloids. The development of the VOD was parallel with the development of the percentage of mitosis; thus, the VOD enabled the Vinca alkaloid-induced effects to be specifically characterized from a morphonuclear point of view. On the other hand, the results show that the mean value of the variance of the optical density was very highly correlated ( $P < 0.001$ ) with the efficiency of the Vinca alkaloids in terms of cytotoxicity. In clinical studies, the analysis of the development of this parameter would make it possible to assess the response to chemotherapy in the case of patients treated with Vinca alkaloids.

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## Vinorelbine in pre-treated advanced head & neck squamous cell carcinoma. A phase II study.

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**BACKGROUND:** There are few moderately active single-agents for the treatment of recurrent or metastatic head & neck cancer. Thus, the identification of novel active agents is warranted. We performed the present phase II trial to evaluate activity and toxicity of vinorelbine (VNB) in previously treated patients with advanced head & neck cancer. **PATIENTS AND METHODS:** 16 patients entered the study, 15 of whom were evaluable. The main characteristics were: M/F = 14/1; median age of 58 yrs (18-67); median PS (Karnofsky score) of 70 (60-100); primitive tumor sites were: oropharynx in 5; larynx in 4, hypopharynx in 3, rhynopharynx in 2, and oral cavity in 1 patient; initial clinical stage was IV in 9, III in 4 and II in 2 patients. Previous treatments were: cisplatinium with concurrent radiotherapy in 6 and cisplatinium + fluorouracil (for at least 2 cycles) in 9 patients. VNB was given at the dose of 20 mg/m<sup>2</sup> i.v. infusion for 1 hr, weekly, for a minimum of 8 doses. Response and toxicity were evaluated after at least 8 doses of VNB. **RESULTS:** Overall, 139 courses of VNB were given (median 9, range 8-19). Objective responses were: partial response in 1 patient (6%); stable disease, lasting at least 2 months, in 4 patients (27%) and progression in the other 10 patients (67%). Three patients had a one week delay in subsequent courses due to severe hematological toxicity. Toxicities observed were: leucopenia of grade IV (W.H.O.) in 2 patients and of grade I-II in 12 patients; granulocytopenia of grade III in 1 patient and of grade IV in 2 patients; grade I-II anemia in 4 patients; grade II phlebitis in 3 patients; grade II constipation in 2 patients, grade I-II peripheral neuropathy in 3 patients, grade I-II nausea and vomiting in 4 patients, and grade II stomatitis in 2 patients. **CONCLUSIONS:** VNB, in this series of heavily pre-treated patients with head & neck cancer, did not reveal an antitumor activity of interest.

Publication Types:

- Clinical Trial